Lupus Nephritis Trials Network

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Membership Meeting

Paris, June, 14 2014

Meeting agenda:

- Welcome – Frédéric Houssiau
- Highlights in 2013 – David Wofsy
- Outcome measures project (ELNT data) – Frédéric Houssiau and David Wofsy
- Next steps –Frédéric Houssiau

Attendees

Approximately 30 LNTN members attended the meeting.

Brief Summary

I. **Highlights in 2013**

a. New Staff: Dawn Smilek, MD, PhD has joined LNTN as Medical/Scientific Director. Dawn is an Associate Director of Clinical Development at the Immune Tolerance Network (ITN). She has had a key role in the development, conduct of a number of ITN trials including CALIBRATE and ACCESS. She will continue to devote 90% of her time to ITN trials, while devoting 10% time to providing the same experience, talent and expertise to LNTN.

b. Three LNTN Endorsed Trials in Progress/Development – All using rituximab, but with different approaches.

1. Rituximab in LN with Remission as a Goal (RING)

   In progress. 5 sites have been activated; 4 participants enrolled to-date out of planned 200; 18 European countries, 4 South American, Japan and Morocco sites are planned. Trial implementation challenges have included rituximab procurement and regulatory issues.

2. Rituximab Plus MMF Without Oral Steroids (RITUXILUP)

   Trial nearing initiation. Protocol complete and IRB approval in place at one UK site; European and US sites are planned; target enrollment start is late 2014.

3. Rituximab Followed by Belimumab to Promote Return of a Non-Autoimmune B Cell Repertoire (CALIBRATE)

   Trial nearing initiation. Collaboration among ITN and Genentech; protocol complete and IND under review by FDA; US sites only due to NIH sponsorship; target enrollment start is late 2014.

c. New Projects

1. Analysis of clinical data and electron microscopic findings on renal biopsy before and after treatment. PI, Iva Gunnarsson. Concept proposal reviewed by Protocol Review Committee during 2013 cycle. Distribution to membership is pending.

2. Accelerating Medicines Partnership (AMP) in RA and Lupus
http://www.niams.nih.gov/Funding/Funded_Research/AMP_RA_Lupus/default.asp
LNTN has submitted a grant application as a combined technology and clinical site.

d. Outcomes Measures Project Expanded

- Extensive involvement throughout the network
- Important collaborations (ASN, KHI, FDA, ELNT)
- First report (at EULAR: Poster presentation or oral presentation see below)

e. LNTN Website Launch

Website launched June 2013 www.lupusnephritis.org. Membership requests and proposal submissions both can occur via the website. Approximately 50 new LNTN members have joined since the website was launched. LNTN membership currently stands at 156 members from 31 countries.

II. Outcomes Measures Project (ELNT/LNTN data analysis collaboration)

Key questions:

- Do the results of clinical trials correlate with long-term preservation of renal function?
- If so, what definition of renal response in a trial correlates best with long-term preservation of renal function?
- How long does a trial need to be in order for the result to correlate with long-term outcome?

Conclusions:

- Improvement (or lack of improvement) in proteinuria in ELNT correlated more closely with long-term preservation of renal function than composite outcome measures that include either serum creatinine or microscopic hematuria.
- Complete response after 12 months of treatment in ELNT correlated better with preservation of renal function than partial response.
- Clinical status 3 or 6 months after initiation of therapy did not correlate as well with long-term preservation of renal function as clinical status at 12 months.
- CR status after initiation of therapy correlated closely with good long-term outcome at all time points (3, 6, and 12 months), but the correlation between

NR status and poor outcome was much stronger at 12 months than it was at the earlier time points.

III. **Next Steps**

The next LNTN concept proposal submission cycle will be opened on 01 July 2014 and will remain open through 10 September 2014. Proposals will be reviewed prior to the ACR meeting in November and responses will be sent to investigators shortly thereafter.